

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No. 0:24-60437-CIV-DIMITROULEAS/HUNT

ZACHARY KELLY,

Plaintiff,

vs.

PHILIP MORRIS INTERNATIONAL INC.,
and SWEDISH MATCH NORTH AMERICA LLC,

Defendants.

**DEFENDANT SWEDISH MATCH NORTH AMERICA LLC'S MOTION TO DISMISS
AND MEMORANDUM OF LAW IN SUPPORT**

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Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendant Swedish Match North America LLC respectfully moves to dismiss the Complaint filed by Plaintiff Zachary Kelly (ECF No. 1) in its entirety.

I. INTRODUCTION

Swedish Match is a leading seller of smokeless nicotine products and is committed to its vision of “[a] world without cigarettes.” In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (TCA), acting in part to promote the development and marketing of products that have the potential to reduce risks associated with exposure to the harmful chemicals in cigarette smoke. ZYN is such a product: an oral pouch that delivers nicotine but does not generate the harmful chemicals created by tobacco combustion in cigarettes. ZYN’s labeling and advertising carries the federally-mandated warning: “This product contains nicotine. Nicotine is an addictive chemical.” There is simply no basis for a product that complies with the mandated warning requirements and is otherwise designed to fall within the category of the very nicotine products Congress intended to promote to be deemed a defective product under Florida law.

Plaintiff nevertheless seeks to represent nationwide and Florida-specific classes of ZYN purchasers to challenge the manufacture, labeling, marketing, and sale of ZYN. Despite the nicotine warning on every package, the Complaint alleges product liability, negligence, and fraud claims, based on Plaintiff’s allegation that ZYN delivers a high “dose” of nicotine, leading to addiction and potential nicotine-related health issues. He seeks various relief, including a medical monitoring remedy. The Complaint is deficient in multiple ways.

First, Plaintiff’s product liability and negligence claims based on an alleged failure to warn are preempted by federal law regulating the labeling of “tobacco products.” *Second*, to the extent Plaintiff’s product liability and negligence claims are not preempted, the complaint lacks any allegation that could support a failure-to-warn theory in the face of the well-known addictive nature

of nicotine and the prominent, federally-mandated nicotine warning. And long-established precedent holds that products are not defective simply because they may be inherently risky. *Third*, Plaintiff does not come close to pleading a fraud claim with the required particularity. *Finally*, Plaintiff does not satisfy the standard for medical monitoring relief under Florida law.

This lawsuit is, at its essence, an attack on any nicotine-containing product developed to be a better alternative to cigarettes simply because it contains nicotine. The risks from that nicotine do not make those products defective under Florida law. Plaintiff's Complaint should be dismissed in its entirety.

II. BACKGROUND AND SUMMARY OF PLAINTIFF'S ALLEGATIONS

ZYN "is an oral nicotine product" that is intended to be placed behind the user's lip. Compl. ¶¶ 1, 15. The Complaint concedes that ZYN does not contain tobacco, although it asserts that the nicotine in ZYN is "derived from tobacco." *Id.* ¶ 16. In accordance with FDA regulations, all of ZYN's packaging and marketing contain a prominent warning stating: "**This product contains nicotine. Nicotine is an addictive chemical.**" *See id.* ¶¶ 2–3, 22, 27, 44.

Plaintiff Zachary Kelly alleges that he "began using ZYN when he was a teenager in or about 2019," and that he "is addicted to the nicotine contained in ZYN and has suffered personal injuries as a result of his ZYN use." *Id.* ¶ 7. He asserts four causes of action against Swedish Match: (1) strict-liability design defect; (2) strict-liability failure to warn; (3) negligence; and (4) fraud. *Id.* ¶¶ 54–117. He seeks to certify three proposed classes: (i) "All persons who purchased, in the United States, ZYN products"; (ii) "All residents of Florida who purchased ZYN products"; and (iii) "All residents of Florida who, at the time of their use of ZYN products, were under the age of 21, and who procured and used ZYN products." *Id.* ¶ 45.

Plaintiff asserts that ZYN "delivers a potent dose of nicotine" and is "unreasonably dangerous, and therefore defective, particularly for youth" because it "creates and sustains an

addiction to nicotine.” *Id.* ¶¶ 20, 35. Plaintiff then alleges that the prominent, FDA-required nicotine warning is “entirely insufficient” to communicate the risk of nicotine addiction and other health effects of nicotine use. *See id.* ¶ 44.

Plaintiff discloses little about his own ZYN use. He alleges that he “began using ZYN when he was a teenager,” is addicted to nicotine, and “was influenced by ZYN’s marketing and advertising, which drove purchases” of ZYN. *Id.* ¶ 7. But he does not identify the advertisements he supposedly saw, what they said, when he saw them, what was wrong with them, or how he relied on or was influenced by them. Nor does Plaintiff describe his alleged injuries other than asserting that he is “addicted” to nicotine and has suffered “personal injuries.” *Id.*

III. ARGUMENT

To survive a Rule 12(b)(6) motion to dismiss, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v Twombly*, 550 U.S. 544, 570 (2007)). To meet that standard, the plaintiff must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* Nor will “‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Id.* (alteration in original) (quoting *Twombly*, 550 U.S. at 557). A claim that is preempted by federal law fails to state a claim upon which relief can be granted under Rule 12(b)(6). *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1141, 1149, 1175 (S.D. Fla. 2020) (granting Rule 12(b)(6) motion to dismiss claims as preempted by the Food, Drug, and Cosmetic Act).

Claims sounding in fraud or mistake must satisfy the heightened pleading standard under Federal Rule of Civil Procedure 9(b), which requires a plaintiff to “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b); *see also Wilding v. DNC Servs.*

Corp., 941 F.3d 1116, 1127–28 (11th Cir. 2019). This includes stating: (1) “the precise statements, documents, or misrepresentations made”; (2) “the time, place and person responsible for the statement”; (3) “the content and manner in which these statements misled” the plaintiff; and (4) “what the defendants gained by the alleged fraud.” *Wilding*, 941 F.3d at 1128 (citation omitted). In other words, Rule 9(b) requires a plaintiff to identify specifically “the who, what, when, where, and how of the fraud alleged.” *Omnipol, A.S. v. Multinational Def. Servs., LLC*, 32 F.4th 1298, 1307 (11th Cir. 2022). “A bare allegation of reliance on alleged misrepresentations, bereft of any additional detail, will not suffice under Rule 9(b).” *Wilding*, 941 F.3d at 1128.

Plaintiff’s claims should be dismissed in their entirety.

A. Plaintiff’s Failure-to-Warn and Negligence Claims Concerning ZYN’s Labeling and Packaging Are Preempted

Plaintiff’s claims relating to ZYN’s labeling and packaging are preempted. Congress may expressly preempt state laws that impose different standards than those set by Congress or its delegatee. *Kansas v. Garcia*, 140 S. Ct. 791, 801 (2020). Congress did just that in the TCA when it delegated authority to the FDA to regulate the labeling of products like ZYN.

The TCA includes an express preemption provision that bars any state from imposing “*any requirement which is different from, or in addition to*” the FDA’s requirements relating to “*labeling*.” 21 U.S.C. § 387p(a)(2)(A) (emphasis added).¹ “[L]abeling” is defined as “all labels

¹ The preemption provision states: “No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product . . . labeling.” 21 U.S.C. § 387p(a)(2)(A). The preemption provision includes a savings clause and preservation clause. The savings clause exempts certain categories of regulation from preemption; in particular, it “does not apply to requirements relating to the . . . advertising and promotion of” tobacco products. 21 U.S.C. § 387p(a)(2)(B). Except as prohibited by the preemption provision, the preservation clause otherwise allows states to impose and enforce laws and regulations “relating to or prohibiting the sale, distribution, possession, . . . advertising and promotion of, or

and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(k)-(m). The FDA has promulgated a “labeling” requirement that is applicable to ZYN,² and mandates that ZYN “bear[] the following required warning statement on the package label: ‘WARNING: This product contains nicotine. Nicotine is an addictive chemical.’” 21 C.F.R. § 1143.3(a)(1) (hereinafter “Nicotine Label Requirement”). Because the FDA has exercised its delegated authority to require a specific warning on ZYN, the plain language of the TCA preempts any claim that would require additional or different warnings than the Nicotine Label Requirement.³

Federal courts have repeatedly held that the plain language of the TCA preempts any additional or different state label requirement where, as here, the FDA has required a specific warning. As one court explained in finding state-law claims against the manufacturer of e-cigarettes preempted: “[T]he clear and unambiguous language of the preemption provision of the TCA preempts states from requiring any particular ‘labeling’ of tobacco products.” *In re Fontem US, Inc.*, 2016 WL 6520142, at *2 (C.D. Cal. Nov. 1, 2016). That is because “by the express terms of 21 U.S.C. § 387p(a)(2)(A), no State can impose ‘any requirement which is different from, or in addition to’ the FDA’s requirements regarding the written, printed, or graphic matter that appears on tobacco products or accompanies those products.” *Id.* at *3. The *Fontem* court rejected the

use of tobacco products.” 21 U.S.C. § 387p(a)(1).

² The FDA’s labeling requirement applies to “covered tobacco products other than cigars.” 21 C.F.R. § 1143.3(a)(1). FDA regulations define a “covered tobacco product” as “any tobacco product deemed to be subject to the [FDCA] pursuant to § 1100.2 of this chapter.” 21 C.F.R. § 1143.1. ZYN products are so-called “deemed” products. *See* 21 C.F.R. § 1100.2.

³ Preemption may be either express or implied. *See United States v. Alabama*, 691 F.3d 1269, 1281 (11th Cir. 2012). Express preemption exists here because “the text of a federal statute explicitly manifests Congress’s intent to displace state law.” *Id.* In the alternative, implied preemption exists because there is sufficient evidence of Congress’s intent to preempt to overcome the presumption against preemption of state law. *See id.* at 1281–82.

argument that Congress meant to preempt only state-law imposed warnings that conflicted with the federal warning. Instead, it found that Congress’s use of the term “different from, *or in addition to*” in the TCA meant that the provision “sweeps widely” and preempts *any* state-labeling requirement that is not identical to the Nicotine Label Requirement. *See id.* at *4 (quoting *Nat’l Meat Ass’n v. Harris*, 132 S. Ct. 965, 970 (2012)).

This express preemption of any state-labeling requirement is not limited by the TCA’s statement that “[n]o provision [of the relevant portion of the TCA] shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.” 21 U.S.C. § 387p(b). While this provision protects space for state product liability laws, the rule of construction cannot override the “clear and unambiguous language” of the preemption provision. *Fontem*, 2016 WL 6520142, at *2. To read the rule to override the express preemption of state labeling requirements would undermine the stated purpose of the preemption provision to “set national standards” for labeling, Pub. L. No. 111-31, 123 Stat. 1776, 1782 (2009), and would be at odds with longstanding federal policy to preempt nonuniform state-law labeling requirements of tobacco products, *see Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 524 (1992) (plurality) (holding that the Public Health Cigarette Smoking Act of 1969 preempts failure-to-warn claims alleging that products “should have included additional, or more clearly stated, warnings”).

ZYN fully complies with the Nicotine Label Requirement, as shown in every image of ZYN packaging reproduced in the Complaint. *See* Compl. ¶¶ 2–3, 22, 27; *see also id.* at ¶ 44. Plaintiff’s failure-to-warn claim rests on the assertion that Swedish Match failed to provide a host of additional warnings on ZYN labels or packaging. Compl. ¶ 74 (listing allegedly missing warnings). And Plaintiff’s negligence claim likewise rests on the theory that Swedish Match acted negligently by failing to provide additional warnings beyond the federally-mandated nicotine

warning. *Id.* ¶ 95. Because both of these state-law claims would require additional warnings beyond those mandated by the FDA, they are expressly preempted by the TCA. Plaintiff's failure-to-warn and negligence claims must be dismissed on that basis alone. *See id.* ¶¶ 70–83 (Cause of Action II, Strict Liability – Failure to Warn); *id.* ¶¶ 84–100 (Cause of Action III, Negligence).

B. Plaintiff Fails to Allege a Plausible Failure-to-Warn Claim

Plaintiffs' failure-to-warn claim is preempted, but even if it were not, Plaintiff fails to state a plausible failure-to-warn claim. To state a strict liability failure-to-warn claim, a plaintiff must plausibly plead, among other elements, that the warnings accompanying the item were inadequate, which requires the plaintiff to "describe the manner in which the warning was inadequate." *Tsavaris v. Pfizer, Inc.*, 2016 WL 375008, at *3 (S.D. Fla. Feb. 1, 2016) (citing *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 602 (11th Cir. 2008)). A plaintiff must also plausibly plead "that the inadequacy of the warning proximately caused his injury." *See Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009). Plaintiff's failure-to-warn claim satisfies neither of these requirements.

1. Plaintiff Does Not Plead the Warnings Were Inadequate

Plaintiff lists eight warnings that ZYN's labeling, packaging, and marketing allegedly failed to provide, *see* Compl. ¶¶ 72–74, but fails to set forth any allegations that show why ZYN's existing warnings are inadequate.

Every single ZYN package informs potential purchasers that ZYN "contains nicotine" and that "[n]icotine is an addictive chemical." *See id.* ¶¶ 2–3, 22, 27. Yet the thrust of the warnings that Plaintiff alleges are missing also relate to nicotine. For example, Plaintiff asserts that the following warnings are missing: (1) "ZYN causes, maintains or aggravates nicotine addiction"; (2) ZYN "increase[s] exposure to nicotine"; (3) "ZYN is a nicotine delivery device"; and (4) nicotine is "derived from tobacco." *See id.* ¶ 74. All of these proposed nicotine warnings are

subsumed by ZYN's existing warnings.

Plaintiff alleges that ZYN's warnings should include more details about different types of potential harm, but a failure-to-warn claim cannot be premised on the failure to warn against every possible permutation of harm that could be caused by a potentially harmful product. *See Ferayorni v. Hyundai Motor Co.*, 711 So. 2d 1167, 1172 (Fla. 4th DCA 1998) (recognizing that "manufacturers are not required to warn of every risk which might be remotely suggested by any obscure tidbit of available knowledge"). As one court explained in the context of alcohol warnings, "[i]t would be next to impossible to create an effective warning label that would warn of the myriad combinations of alcohol use and of human characteristics that might contribute to alcoholism. And, even if it could be done, it would be unnecessary, because the danger of alcoholism is subsumed in the general dangers of alcohol commonly known to the public." *Brown v. Miller Brewing Co.*, 2014 WL 201699, at *9 (D. Idaho Jan. 17, 2014).

In any event, simply listing out potential additional warnings in a complaint is not sufficient. Plaintiff must allege facts that "describe the manner in which the [existing] warning [is] inadequate." *Tsavaris*, 2016 WL 375008, at *3 (citing *Bailey*, 288 F. App'x at 602). He has not even attempted to do so, and this failure should result in dismissal of his failure-to-warn claim. *See Wright v. Howmedica Osteonics Corp.*, 741 F. App'x 624, 626 (11th Cir. 2018) (affirming dismissal of a failure-to-warn claim as insufficiently pled because the plaintiff failed to explain how the existing label was inadequate); *Bailey*, 288 F. App'x at 609 (same).

2. Plaintiff Insufficiently Pleads Causation

Plaintiff's failure-to-warn claim should also be dismissed because Plaintiff fails to plausibly allege "that the inadequacy of the warning proximately caused his injury." *See Hoffmann-La Roche*, 27 So. 3d at 77. Plaintiff makes conclusory allegations that he was "injured as a direct and proximate result of Defendants' failure to warn because [he] would not have used

or purchased ZYN had [he] received adequate warnings and instructions,” and the alleged failure to warn “was a substantial contributing factor in causing the harm to Plaintiff.” Compl. ¶¶ 81–82.

The Complaint, however, includes no facts that make these allegations plausible. If anything, the pleaded facts demonstrate that a causal link between the allegedly missing warnings and Plaintiff’s use of ZYN is *implausible*. For example, Plaintiff asserts that ZYN should have a warning that it is not to be used by individuals under 26 years of age, *id.* ¶ 74, but he acknowledges that he began using ZYN as “a teenager,” *id.* ¶ 7, even though the minimum age for purchasing ZYN in the United States is 21 years and ZYN is intended for use by those 21 and older, *see* 21 U.S.C. § 387f(d). It is implausible that someone who chose to use a product banned for his age group of under-21 would have been deterred by an under-26 warning.

Nor does Plaintiff explain how any of his other proposed warnings about nicotine and its effects would have altered his purchasing decision, especially given that the more detailed warnings listed in the Complaint are subsumed within the general warning of nicotine’s addictiveness and the age restriction on the product. *See, e.g., Brown*, 2014 WL 201699, at *9.

Because Plaintiff fails to allege that any inadequate warning is plausibly tied to his claimed injuries, his failure-to-warn claim must be dismissed. *See Iqbal*, 556 U.S. at 678.

C. Plaintiff Fails to Allege a Plausible Design-Defect Claim

To state a design-defect claim, Plaintiff must allege, among other things, that “the product has a defect that renders it unreasonably dangerous” and that “the unreasonably dangerous condition is the proximate cause of [his] injury.” *Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999); *accord West v. Caterpillar Tractor Co.*, 336 So. 2d 80, 87 (Fla. 1976). It is not enough to plead that using a product may cause harm; that would improperly make a manufacturer or distributor “an insurer of all foreseeable accidents which involve its product.” *Hernandez v. Altec Env’t Prods., LLC*, 903 F. Supp. 2d 1350, 1360 (S.D. Fla. 2012) (quoting *Husky Indus., Inc.*

v. Black, 434 So. 2d 988, 991 (Fla. 4th DCA 1983)). Nor is a product liability action maintainable “merely because the design used was not the safest possible.” *Id.* (quoting *Husky*, 434 So. 2d at 991). Plaintiff has failed to plead a cognizable defect, or that any defect proximately caused his alleged injuries. His design-defect cause of action (Cause of Action I) must be dismissed.

1. Plaintiff Fails to Plead Facts Supporting a Design Defect

In Florida, a plaintiff may plead a design-defect claim under either a “consumer expectations” or a “risk utility” theory. *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 512 (Fla. 2015); *accord Jennings*, 181 F.3d at 1255. Regardless of which theory a plaintiff pursues, his complaint “must contain factual allegations about what was in fact defective about the product.” *Shapiro v. NuVasive, Inc.*, 2019 WL 5742159, at *2 (S.D. Fla. Nov. 5, 2019) (quoting *Witt v. Howmedica Osteonics Corp.*, 2013 WL 6858395, at *2 (S.D. Fla. Dec. 30, 2013)); *see also Gomez v. Pfizer, Inc.*, 675 F. Supp. 2d 1159, 1163 (S.D. Fla. 2009) (dismissing a complaint based in part on the ground that there was a lack of “factual allegations suggesting what was in fact defective about the products”). Here, Plaintiff sets forth a handful of boilerplate allegations that fail to plausibly state a claim under either the consumer expectations or the risk-utility theory.

(a) Plaintiff Fails to Plead Design Defect Under the Consumer Expectations Test

Plaintiff fails to state a claim under the consumer expectations test because he does not describe how ZYN “failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.” *See Aubin*, 177 So. 3d at 503 (citing Restatement (Second) of Torts § 402A (1965)). This standard “requires consideration of the ordinary consumer’s expectations.” *See Jennings*, 181 F.3d at 1255 (in claim that defective lighter allowed child to light pajamas on fire, consumer expectations for the lighter were judged from “the perspective of an ‘ordinary consumer’” of lighters, and “not judged from a child’s perspective”).

The Complaint alleges that “ZYN is designed to cause and sustain nicotine addiction, delivers a potent amount of nicotine, and is likely to cause” various injuries. Compl. ¶ 62. But the Complaint contains no allegations, of any kind, about the expectations of the ordinary consumer who seeks out a nicotine delivery product or how ZYN does not meet those expectations. *See id.*

Instead, the Complaint alleges facts under which it would be facially implausible for the ordinary consumer to be unaware that ZYN contains nicotine, the concentration of nicotine, or that nicotine is addictive. The Complaint concedes that: (1) ZYN’s packaging prominently discloses that ZYN comes in either 3 or 6 milligram nicotine concentrations per pouch, *id.* ¶ 2; (2) it publicly has been known for decades that nicotine is addictive, *id.* ¶ 35; and (3) every consumer of ZYN would have seen the prominent warning that the product “contains nicotine” and “[n]icotine is an addictive chemical,” *id.* ¶ 44. Plaintiff fails to set forth any allegations that ordinary consumers, exposed to these warnings and equipped with the common knowledge of nicotine’s addictiveness, expected ZYN not to contain nicotine, to contain a different amount of nicotine, or nicotine not to be addictive—or in any other way held expectations that were unmet by ZYN. Nor is there any allegation that ZYN actually contains a different amount of nicotine than advertised. This failure to plead a disconnect between consumers’ expectations and what consumers received dooms Plaintiff’s attempt to plead a design-defect claim based on consumer expectations. *See Aubin*, 177 So. 3d at 503; *see also Gomez*, 675 F. Supp. 2d at 1163 (simply alleging that “products were ‘defectively designed . . . because [their] intended use resulted in a substantial and unreasonable likelihood of causing [disease], which rendered [them] unreasonably dangerous for [their] intended use,’” was insufficient and “amount[ed] to no more than bare legal conclusions”).

Plaintiff clearly intends to mimic the complaints in the multidistrict litigation involving the JUUL electronic vape device—but the JUUL case actually underscores the defects in this

Complaint. The JUUL product heats a nicotine-containing liquid and delivers a vapor for the user to inhale. The JUUL MDL court declined to dismiss a design-defect claim under the consumer expectation test because JUUL’s packaging stated that the liquid-containing pods contained “5% nicotine,” but the plaintiffs alleged that “JUUL’s pods contain 6.2% nicotine salt, rather than the 5% nicotine advertised [on the label].” *Colgate v. JUUL Labs, Inc.*, 345 F. Supp. 3d 1178, 1193 (N.D. Cal. 2018) (citing FAC ¶ 83). The court found that the plaintiffs sufficiently stated a design-defect claim based on the concrete allegation that JUUL’s pods “would deliver 20% more nicotine” than consumers would reasonably expect from reading the label. *Id.* In contrast, Plaintiff here alleges only that ZYN contains nicotine and nicotine is addictive. That is exactly what ZYN, consistent with federal requirements, states on its packaging. Plaintiff does not, and cannot, allege a misalignment between the prominent warnings that ZYN “contains nicotine” and “[n]icotine is an addictive chemical” and consumers’ expectations of what ZYN contains.⁴

(b) Plaintiff Fails to Plead Design Defect Under the Risk-Utility Test

Plaintiff also fails to state a claim under a risk-utility theory because he does not allege any facts that show that “the risk of danger in [ZYN’s] design outweighs the benefits” or that “alternative safer designs exist.” *Aubin*, 177 So. 3d at 498, 511.

To begin, Plaintiff does not allege that “there [is] something wrong with the product” separate and apart from its intrinsic function of delivering nicotine. *Tuosto v. Philip Morris USA Inc.*, 2007 WL 2398507, at *12 (S.D.N.Y. Aug. 21, 2007) (citation omitted). Plaintiff was required to allege more than that ZYN contains nicotine and nicotine is intrinsically harmful, but did not do

⁴ Plaintiff also alleges that “ZYN was sold in a defective condition” because “Defendants failed to adequately warn about the risk of nicotine addiction.” Compl. ¶ 58. But this repackaged failure-to-warn claim is not cognizable under a design-defect theory. *See Gomez*, 675 F. Supp. 2d at 1163 (noting that defective design and failure to warn “are distinct theories”). The failure-to-warn theories are both preempted and inadequately pleaded (as discussed above).

so. *See Town of Lexington v. Pharmacia Corp.*, 133 F. Supp. 3d 258, 269 (D. Mass. 2015) (citing *Johnson v. Brown & Williamson Tobacco Corp.*, 345 F. Supp. 2d 16, 20 (D. Mass. 2004)) (“The fact that smoking causes cancer, however, does not by itself prove that cigarettes are defectively designed.”). The intrinsic risks of nicotine do not make the product defective.

Even if Plaintiff could overcome this threshold issue, neither of Plaintiff’s two risk-utility allegations are sufficient to state a design-defect claim. First, Plaintiff claims that “risks inherent” in ZYN might have been minimized “by designing products that delivered less nicotine.” Compl. ¶¶ 63–64. But “[a] product is not defective for performing in the manner that it was designed.” *Marzullo v. Crosman Corp.*, 289 F. Supp. 2d 1337, 1343 n.7 (M.D. Fla. 2003) (BB gun not defective for firing BBs with the velocity it was designed to deliver—despite argument that velocity was dangerous). ZYN is designed to deliver nicotine, as are cigarettes and other smokeless tobacco products. ZYN’s packaging discloses the concentration of nicotine per pouch. Compl. ¶¶ 2, 19. The fact that ZYN contains nicotine does not render the product defective—that is the intended design of the product.

Second, Plaintiff alleges that ZYN could have been designed without “flavors that attract youth like Plaintiff,” *id.* ¶ 64, although he tellingly does not allege what flavor purportedly attracted him to the product or that the availability of some particular flavor caused him to use ZYN. Plaintiff does not allege that the addition of flavors makes ZYN more harmful to consumers. *Compare, e.g., Aregood v. Givaudan Flavors Corp.*, 904 F.3d 475, 479 (7th Cir. 2018) (design-defect claim based on allegation that butter flavoring contained a harmful chemical), *abrogated on other grounds by Kaiser v. Johnson & Johnson*, 947 F.3d 996 (7th Cir. 2020). Plaintiff’s theory instead appears to be that he was “enticed by” flavors to use ZYN, Compl. ¶ 6, but the risk he identifies in the product is the risk from *nicotine*, not flavors, and the

presence of nicotine is not a defect, *supra* 12–13. In other words, the addition of flavors is not a product defect because Plaintiff does not and cannot allege that changing the flavor would make consumption of the product any safer.

Nor is Plaintiff’s allegation that flavors “are known to entice underage users” enough to make out a product-defect claim. Compl. ¶ 30. “[F]or strict liability to apply to a manufacturer, the manufactured product at issue ‘must have been used for the purpose intended.’” *Hernandez*, 903 F. Supp. 2d at 1359 (citation omitted). ZYN is not intended for underage use; the “intended use” under Florida law does not include “unintended uses,” even if those uses were reasonably foreseeable. *Id.* As the Eleventh Circuit explained in rejecting a design-defect claim for a non-child-proof lighter, because use of the lighter by a child who started a fire “was not its intended use,” the manufacturer could not be strictly liable for the resulting injuries, “even if such use was reasonably foreseeable.” *Jennings*, 181 F.3d at 1256.

Moreover, even if the addition of a flavor could be a defect, “[t]he risk-benefit analysis requires consideration of the ‘normal public expectation of danger.’” *Id.* at 1255 (citation omitted). But Plaintiff does not, and cannot plausibly, allege that flavors change the normal public expectation of the risks of nicotine when the product carries a prominent nicotine warning and other tobacco-free nicotine products that have long been available—such as other smokeless products—also come in flavors.

More broadly, Plaintiff’s inability to plead that ZYN has been manipulated to create a product that is more dangerous than traditional tobacco products or other nicotine pouch products, distinguishes this case from cases in which a tobacco design-defect claim survived a motion to dismiss. In those cases, the plaintiffs set forth specific factual allegations that the tobacco product in question had been made more harmful than a traditional cigarette because of

some manipulation of the product. *See, e.g., Izzarelli v. R.J. Reynolds Tobacco Co.*, 136 A.3d 1232, 1234 (Conn. 2016) (collecting cases). The same is true of the JUUL case, where the court found that the plaintiff’s risk-utility claim, like the consumer expectations claim, was premised on the concrete allegations that JUUL’s product contained “more nicotine salt than advertised” and therefore “deliver[ed] 30% more nicotine per puff than a combustible cigarette,” which resulted in a product that was allegedly more addictive than a traditional cigarette. *Colgate v. JUUL Labs, Inc. (Colgate II)*, 402 F. Supp. 3d 728, 746 (N.D. Cal. 2019).

Plaintiff does not, and cannot, make a similar allegation that ZYN has been modified in some way to make it more addictive, or more dangerous, than traditional cigarettes, traditional smokeless tobacco, or other nicotine pouch products. As a result, he fails to allege that “there [is] something wrong with the product” beyond the fact that it delivers nicotine and therefore causes the effects associated with nicotine. *Tuosto*, 2007 WL 2398507, at *12 (citation omitted). These allegations fail to state a design-defect claim under the risk-utility theory.

2. Plaintiff Fails to Adequately Plead a Causal Nexus Between Any Alleged Design Defect and His Alleged Injuries

Plaintiff’s design-defect claim independently fails because he does not sufficiently plead that the purported defect was the proximate cause of his injury. *See Jennings*, 181 F.3d at 1255.

The Complaint’s causation allegation simply repeats the legal standard, asserting that “Plaintiff was injured as a direct and proximate result of ZYN’s defective design” and that the allegedly “defective design of ZYN was a substantial factor in causing Plaintiff’s harms.” Compl. ¶ 68. But restating the legal standard fails to plausibly plead causation. *See Sparks v. Medtronic, Inc.*, 2021 WL 2649235, at *2 (M.D. Fla. June 28, 2021) (a “conclusory statement that as a direct and proximate result of the design defect, [plaintiff] suffered injury and was damaged” did not sufficiently allege causation).

Plaintiff was required to allege how ZYN's alleged defect caused his claimed injuries—addiction and “personal injuries.” Compl. ¶ 7. The only alleged defects Plaintiff asserts are (1) a high “dose” of nicotine and (2) ZYN's flavors. He pleads no facts to support that either the allegedly high “dose” of nicotine, as opposed to some ordinary “dose” of nicotine, or ZYN's flavors, caused his addiction. As to his alleged “personal injuries,” the Complaint never identifies what those are, much less identifies the “proximate causal connection,” *see West*, 336 So. 2d at 87, between those injuries and either some defective “dose” of nicotine or ZYN's flavors. Plaintiff has therefore failed to allege that his injuries were proximately caused by a legally cognizable defect.

D. Plaintiff Fails to Allege a Plausible Negligence Claim

Plaintiff's third cause of action for negligence is premised on the same theory of liability as his strict products liability claims: that defendants sold a defective product and failed to sufficiently warn of the defects. It fails for the same reasons. “In order to prevail in a products liability action brought under a theory of either strict liability or negligence, a plaintiff must demonstrate that the injuries complained of were caused by a defective product whose defect existed at the time of injury and at the time in which the product left the manufacturer's control.” *Colville v. Pharmacia & Upjohn Co.*, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (citation omitted); *accord Witt v. Stryker Corp. of Mich.*, 648 F. App'x 867, 875 (11th Cir. 2016). Because Plaintiff's strict product liability claims subsume his negligence claim and must be dismissed for failure to plausibly allege a cognizable defect that proximately caused harm to Plaintiff, his negligence claim must also be dismissed. *See Colgate II*, 402 F. Supp. 3d at 752 (dismissing negligent marketing claim that was subsumed by failure-to-warn and design-defect claims).

E. Plaintiff Fails To Plead Fraud with Particularity

Plaintiff fails to plead fraud with the particularity required by Rule 9(b) because he fails to

identify “the who, what, when, where, and how of the fraud alleged.” *Omnipol*, 32 F.4th at 1307.

To state a claim for fraud, Plaintiff must allege: (1) a false statement or omission concerning a material fact; (2) knowledge of the alleged falsity; (3) intent to defraud or induce reliance; and (4) justifiable reliance on the alleged misrepresentation or omission that caused injury. *See Butler v. Yusem*, 44 So. 3d 102, 105 (Fla. 2010). Rule 9(b) requires that Plaintiff set forth those allegations with sufficient particularity. *See Grills v. Philip Morris USA, Inc.*, 645 F. Supp. 2d 1107, 1121 (M.D. Fla. 2009) (holding that Rule 9(b) applies in a diversity fraud action). Yet the Complaint fails to identify, among other things, what advertisements Plaintiff viewed, when he viewed them, or how he relied on them. All of these are required to satisfy Rule 9(b). *See, e.g., Wilding*, 941 F.3d at 1128; *Grills*, 645 F. Supp. 2d at 1124; *In re Toyota RAV4 Hybrid Fuel Tank Litig.*, 534 F. Supp. 3d 1067, 1097 (N.D. Cal. 2021). As a result, Plaintiff fails to plead fraud with enough specificity to “alert[] defendants to the precise misconduct with which they are charged,” *Omnipol*, 32 F.4th at 1307 (internal quotation marks omitted), and therefore fails to comply with Rule 9(b), *e.g., Jackson v. Anheuser-Busch InBev SA/NV, LLC*, 2021 WL 3666312, at *7 (S.D. Fla. Aug. 18, 2021) (“Rule 9(b) requires that Plaintiffs specifically allege more than the vague and conclusory statement that they were induced by the misrepresentation” (internal quotation marks, citation, and alteration omitted)). The fraud cause of action must be dismissed.

First, Plaintiff fails to plead with particularity the “what”—the specific misrepresentations he alleges satisfy the first element of a Florida fraud claim. The Complaint makes the conclusory assertion that Defendants’ advertising was “deceptive,” Compl. ¶¶ 5, 104, 105, but it never identifies any specific advertising Plaintiff allegedly viewed, much less the specific statements in that advertising that Plaintiff contends are deceptive.

All Plaintiff says about the impact of advertising on him is that he “was influenced by

ZYN’s marketing and advertising, which drove purchases.” *Id.* ¶ 7. But that is plainly not enough to meet Plaintiff’s burden to allege specifically “the content of the fraudulent statements or omissions and the manner in which they misled him.” *Grills*, 645 F. Supp. 2d at 1124 (internal quotation marks, citations, and alterations omitted). As courts have repeatedly held, where a plaintiff fails to allege “on which of the [defendant’s] statements [he] relied,” the Complaint must be dismissed. *Wilding*, 941 F.3d at 1128; *see also Toyota RAV4 Hybrid Fuel Tank Litig.*, 534 F. Supp. 3d at 1097 (finding that the requirements of Rule 9(b) were not met where the plaintiffs never alleged that they actually saw the purportedly misleading advertisements).

Second, Plaintiff also fails to specifically plead either “when” or “where” he purportedly saw the advertisements he says were misleading. He asserts only that he began “using ZYN . . . in or about in 2019.” Compl. ¶ 7. But he makes no allegation about when or where he saw any advertising that supposedly caused him to use ZYN.⁵ The fraud cause of action must therefore be dismissed for the independent reasons that Plaintiff has failed to plead “the time and place” of the allegedly misleading advertising. *See Grills*, 645 F. Supp. 2d at 1124.

Third, Plaintiff also fails to set forth any facts that support justifiable reliance. His only reliance allegation is that he “reasonably and justifiably relied on the misrepresentations and/or omissions.” Compl. ¶ 110. That type of “bare allegation of reliance on alleged misrepresentations, bereft of any additional detail, will not suffice under Rule 9(b).” *Wilding*, 941 F.3d at 1128; *accord Toyota RAV4 Hybrid Fuel Tank Litig.*, 534 F. Supp. 3d at 1097 (mere assertion that plaintiff “believed and relied upon [defendant’s] representations” fails to adequately plead reliance). For this reason, too, the fraud cause of action must be dismissed.

⁵ Although the Complaint says ZYN advertising “drove purchases,” Compl. ¶ 7, it conspicuously does *not* allege that Plaintiff himself ever purchased ZYN, much less that he purchased ZYN as a result of allegedly deceptive advertising.

Finally, Plaintiff cannot cure these multiple failings by relying on a theory of fraudulent omission. Rule 9(b) “applies equally to frauds based on affirmative misstatements and misleading omissions.” *Durden v. Citicorp Tr. Bank, FSB*, 2008 WL 2098040, at *6 (M.D. Fla. May 16, 2008) (citing *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1371 (11th Cir. 1997)); *see also Koski v. Carrier Corp.*, 347 F. Supp. 3d 1185, 1196 (S.D. Fla. 2017) (“The Plaintiffs’ claim for fraudulent concealment is subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b).”). A plaintiff alleging fraudulent omission must, therefore, still precisely identify the alleged omissions, the time and place of such omissions, and the manner in which he was misled by the alleged omissions. *See Durden*, 2008 WL 2098040, at *6 (quoting *Brooks*, 116 F.3d at 1371). As already noted, Plaintiff does not identify *any* advertisement that he claims to have viewed, much less identify what information should have been, but was not, included in each such advertisement.

Because Plaintiff has failed to allege the what, when, or where of the purported fraud, including what advertisements he supposedly viewed and what false statements he purportedly relied upon, his fraud claim must be dismissed.

F. Plaintiff Fails to Allege Entitlement to Medical Monitoring

Among other forms of relief, Plaintiff asserts he is entitled to “medical monitoring” for early diagnosis of purported ZYN-induced injuries. *See* Compl., ¶¶ 69, 83, 100, 113, Prayer for Relief. Florida law “does recognize a cause of action for future expenses for medical diagnosis.” *Petito v. A.H. Robins Co.*, 750 So. 2d 103, 105 (Fla. 3d DCA 1999). But nowhere in the Complaint does Plaintiff plead a medical monitoring *cause of action*. *See* Compl. ¶¶ 54–117. This alone is reason to dismiss his request for medical monitoring. *See Jerue v. Drummond Co.*, 2017 WL 10876737, at *14 (M.D. Fla. Aug. 17, 2017) (“Plaintiffs have failed to state a claim for medical monitoring by not pleading it as a standalone claim.”).

Regardless, Plaintiff fails to state a claim for medical monitoring. Such a claim requires establishing the following seven elements:

(1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Wyeth, Inc. v. Gottlieb, 930 So. 2d 635, 640 (Fla. 3d DCA 2006) (quoting *Petito*, 750 So. 2d at 106–07). Plaintiff comes nowhere close to pleading facts to establish each of these elements. The only injury allegations in the Complaint are that Plaintiff suffers from addiction and unspecified “personal injuries.”⁶ Compl. ¶ 7. Plaintiff does not plead any facts regarding the significance or extent of his exposure to nicotine (element 1), and in any event, as discussed, he fails to allege a plausible claim under either a theory of strict liability or negligence (elements 2 and 3). Nor does Plaintiff allege he has any increased risk of a serious latent disease (element 4). Indeed, he does not include a single allegation about his own medical circumstances or demographics. He therefore fails to allege facts that plausibly show that early detection of some disease is possible (element 5) or that a special monitoring regime “is reasonably necessary” (elements 6 and 7). *See Petito*, 750 So. 2d at 107. His request for medical monitoring should be dismissed.

IV. CONCLUSION

Plaintiff's Complaint should be dismissed for failure to state a claim.

⁶ Addiction in and of itself is not a cognizable injury. *See Pic “N” Save v. Parker*, 807 So. 2d 689, 690 (Fla. 1st DCA 2002).

V. REQUEST FOR HEARING

Pursuant to Local Rule 7.1(b)(2), Defendant Swedish Match respectfully requests 20 minutes of oral argument on this motion because the motion raises multiple grounds for dismissal and so that Defendant may respond to any questions the Court may have.

Dated: May 6, 2024

Respectfully submitted,

/s/ Gary A. Orseck

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of May, 2024, I electronically filed the foregoing with the Clerk of Court using CM/ECF. I also certify that the foregoing document is being served this day on the counsel of record or pro se parties on the Service List below via transmission of Notices of Electronic Filing generated by CM/ECF.

By: /s/ Gary A. Orseck

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